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EXAMINER

HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/603,409

Applicant(s)

HOYNS, DIRK V.

Examiner

(Jackie) Tan-Uyen T. Ho

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 6, 14, 15, 24, 25, 30-34 and 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 4, 5 is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-13, 16-23, 26-29, 35-39 and 44-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 recites the limitation "the circumferentially oriented links" in line 6. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation, "a gap defined between the portion of each of the arms that circumscribes a segment of an adjacent arm" is not clear. Perhaps, applicant intended to claim a gap defined between the portion of each of the arms that circumscribes the hub and a segment of an adjacent arm, the gap being of substantially constant width."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-3, 7-13, 16-18, 20-23, 26-29, 35-39 and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Ehr et al. (6,334,870).

In regard to claim 1: Ehr et al. disclose a stent including: (See attachment I, illustration of figures 29 & 30) a plurality of nodes, each node having a central hub and at least three arms extending from the hub, each arm circumscribing the hub and a segment of the next adjacent arm of that node, each arm is connected to an arm of an adjacent node at a transition region; a link between the nodes being defined by the connected arms of the adjacent nodes (figs. 29 and 30).

In regard to claims 2 and 3, wherein the arms in the links of adjacent nodes curve in opposite directions and the links are S-shaped (fig. 30)

In regard to claim 7, wherein the arms of the nodes are arranged generally to define a spiral (figs. 29 & 30)

In regard to claims 8-10, wherein a gap between adjacent arms of a spiral is of substantially constant width up to the transition region (figs. 29 & 30), each of the arms of a node is connected at a root to the hub of the node and each arms of each node is connected to a different one of the adjacent nodes

In regard to claims 11-13, the stent of claim 1 further comprising a plurality of adjacent pairs of nodes lie along radially extending planes and the planes being spaced along the length of the stent, the links between nodes of the pairs lie along the radial planes and extend in a circumferential direction and an additional pairs of adjacent nodes extending along a row that extends generally helically along the stent (fig. 29, see attachment 1)

In regard to claims 16-18 and 20-22, wherein the transition region is disposed at the mid-portion of the link (mid portion of member 12), the stent is formed from stainless steel and the stent has a low profile and expanded diameters adapted to be deployed within a human biliary duct, blood vessel, urological passage (inherent feature).

In regard to claim 23, Ehr et al. disclose a stent (see attachment I, illustration of figures 29) including a plurality of nodes; a central hub for each node, at least three arms extending from the hub; a transition region where each arm being connected to an arm of an adjacent node; a link between the nodes being defined by the connected arms of the adjacent nodes and wherein the stent comprising substantially entirely by the nodes.

In regard to claims 26-29, Ehr et al. disclose the stent (figs. 16 and 29) of claim 23, wherein the nodes are arranged in clusters of six nodes each and the arms of the nodes are arranged generally to define a spiral, the nodes arranged in a plurality of helical row, the nodes in each row being serially connected to each other by a link

In regard to claims 35, Ehr discloses a stent (fig. 16) including a plurality of nodes, each node being connected to three adjacent nodes, each by an individual

generally S-shaped links (fig. 16), a central hub for each node, three arms extending from the hub (fig. 16).

In regard to claim 36, Ehr discloses a stent (fig. 30) including a plurality of nodes, S-shaped links connecting adjacent nodes (fig. 30), a central hub for each node, three arms extending from the hub.

In regard to claims 37-38, Ehr discloses the stent (fig. 29) of claim 1, wherein the nodes is arranged in clusters of six in which two arms of each node are connected to nodes of a cluster and one arm of each of the nodes in that cluster is connected to a node of another cluster.

In regard to claim 39, wherein each of the nodes in the stent is shared by three adjacent clusters.

In regard to claims 45-46, Ehr discloses a stent (fig. 16) including a plurality of nodes, each node having a central hub and three arms extending from the hub, each arm circumscribing the hub and a segment of the next adjacent arm of that node, each arm being connected only to an arm of adjacent node at a transition region, the connected arms of the adjacent nodes defining a substantially continuously curving S-shaped link between those nodes and a gap being of substantially constant width up to the transition region (fig. 16).

In regard to claim 47, a gap defined between the portion of each of the arms that circumscribes the hub and a segment of an adjacent arm, the gap being of substantially constant width (fig. 29).

6. Claims 23, 26-28, 35 and 44-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Ley (6,231,599).

In regard to claim 23, Ley discloses a stent (figs. 1, 5, 7, 14a, 15a, 22a) including a plurality of nodes, each defined by a central hub and three arms, each of the arms in each of the nodes having a portion that circumscribes the hub and a segment of an adjacent arm of that node, the stent being defined substantially entirely by the nodes.

In regard to claim 26, wherein the arms define a generally spiral configuration (figs. 1, 5, 7, 14a, 15a, 22a).

In regard to claim 27, wherein the nodes are arranged in clusters of six nodes each (figs 1 and 22a)

In regard to claim 28, wherein the nodes are arranged along a plurality of helical rows, the nodes in each row being serially connected to each other by a link, each of the nodes in each helical row also being connected, by a link, to a node in each adjacent helical row (figs. 1, 5, 7, 14a, 15a, 22a).

al
In regard to claim 35, Ley disclose a stent including a plurality of nodes, each node being connected to three adjacent nodes, each by an individual generally S-shaped link (fig. 22a), the links and nodes being arranged so that when the stent is expanded from its initial diameter to an expanded diameter, links which are circumferentially oriented will elongate to a greater degree than links oriented in a less circumferential direction (inherent feature).

In regard to claim 44, Ley discloses a stent (^{fig 1}fig. 22a) including: a plurality of nodes, each node having a central hub and three arms extending from the hub, each

arm circumscribing the hub and a segment of the next adjacent arm of that node, each arm being connected only to an arm of adjacent node at a transition region (mid portion of the two connected arm or the S-shaped link) the connected arms of the adjacent nodes defining a link between those nodes.

al In regard to claim 45, Ley discloses a stent (fig. 22a) including: a plurality of nodes, each node having a central hub and three arms extending from the hub, each arm circumscribing the hub and a segment of the next adjacent arm of that node, each arm being connected only to an arm of adjacent node at a transition region, the connected arms of the adjacent nodes defining a substantially continuously curving S-shaped link between those nodes.

In regard to claim 46, Ley discloses a stent (fig. 22a) including: a plurality of nodes, each node having a central hub and three arms extending from the hub, each arm circumscribing the hub and a segment of the next adjacent arm of that node and defining a gap between the adjacent arm, each arm being connected to an arm of adjacent node at a transition region (mid portion of the two connected arm or the S-shaped link), the connected arms of the adjacent nodes defining a link between those nodes and the gap being substantially constant width up to the transition region.

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ehr et al. (6,334,870). Ehr et al. disclose all the limitations of the claims (as described above) except for a metal having shape memory characteristics adapted to enable the stent to expand in response to a thermal event being used to form the stent. It would have been obvious matter of design choice to make the stent of Ehr et al. from a metal having shape memory characteristics as claimed, since applicant has not disclosed that having the stent make from the claimed material solves any stated problem or is for any particular purpose and it appears that the stent would perform equally well in either materials, stainless steel or a metal having thermal shape memory.

Allowable Subject Matter

9. Claims 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a stent including a plurality of nodes arranged in a hexagonal cluster, each node having a central hub and three arms extending from the hub, each arm circumscribing the hub and each arm being connected, at a transition region, to an arm of an adjacent node.

Response to Amendment

10. Applicant's arguments filed 11/20/2002 have been fully considered but they are not persuasive.

Page 6, lines 12-17 of the amendment, applicant argues that the claim does not call for "at least" three arms. Rather, it calls for "three arms", no more and no less." Examiner respectfully disagrees. Claim 1 calls for "three arms extending from the hub," which limits a hub including at least three arms but it does not limit a hub that has more than three arms extending thereto.

Page 6, lines 17-27, applicant argues that Ehr '870 (figs. 29 and 30) fails to disclose "a plurality of nodes, each having a central hub and three arms, with each arm being connected, at a transition region, to an arm of an adjacent node." Examiner respectfully disagrees. In figs. 29 and 30, Ehr discloses a plurality of nodes, each having a central hub and three or more arms extending thereto, two arms of adjacent node being connected at a transition region (the mid portion of a sinusoidal expandable member 12, see attachment 1).

Page 7, lines 1-5, applicant argues that "the action does not point out where the Ehr '870 patent discloses the claimed additional pairs of adjacent nodes that extend along a generally helical row. Ehr '870 fails to anticipate claim 13." Examiner respectfully disagrees. Figs. 29 and 30 of the Ehr reference show additional pairs of adjacent nodes that extend along a generally helical row (see attachment 1).

Also, new ground of rejections for amended claims 23, 35 and new claims 44-48 are presented above.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on **MULTIFLEX** Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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(Jackie) Tan-Uyen T. Ho
January 30, 2003



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